Kansas	**STATE BOARD OF PHARMACY** 800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056 pharmacy@ks.gov Fax (785) 296-8420	**REGISTRATION APPLICATION:** **Manufacturer** Form BA-04

All applications must be typed, be complete, and include all fees and supporting documentation before they will be processed by staff.

FEES

Enclose a check or money order payable to the Kansas State Board of Pharmacy in the amount of $350.00. Fees are nonrefundable.

INSTRUCTIONS

This form may be used for resident and non-resident manufacturers, as well as virtual facilities. Please include a history of any/all pharmacy, distributor, or manufacturer affiliations.

Non-resident facilities: Attach a copy of the most recent inspection report conducted at the current physical location within the past three years by the state of residence, NABP, or FDA.

Virtual facilities: Attach a list of all products manufactured, as well as the name, address, email address, and FEI number of all FDA-registered contract manufacturers.

OWNERSHIP

The Owner is considered the "applicant" for purposes of this form. If the Owner is a corporate or other legal entity, please complete and attach the appropriate Ownership Form (S-310 Partnership, S-320 LLC, or S-330 Corporate). If owned by other LLCs, partnerships, holding companies, etc., please submit information down to a person level of ownership.

Please indicate if this is a new application or a change:

☐ New Application Change (Check all that apply): ☐ Address ☐ Ownership ☐ Name

Previous registration number: _____ Effective date of change: _____

OWNER INFORMATION

Name		Other States Registered (abbrev.)	
Address			
City	State	Zip	County
Phone	Fax		Email

Ownership Type:

☐ Individual Provide SSN: _____ ☐ Government Entity Provide FEIN: _____

☐ Partnership ☐ LLC ☐ Corporation

Complete and attach the appropriate Ownership Form (S-310 Partnership, S-320 LLC, or S-330 Corporate)

MANUFACTURING FACILITY INFORMATION

Trade/Business Name (printed on license)		Hours of Operation	
Physical Address (non-residential)			
City	State	Zip	County
Phone	Fax		Email

Designate where all formal correspondence, notices, and renewals should be sent:

☐ Owner ☐ Physical Location ☐ Authorized Agent

Initials: _____ **OFFICE USE ONLY**

Permit #: _____ Fee: $_____ Date: _____ Check #: _____

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AUTHORIZED AGENT INFORMATION (For partnerships, LLCs, nonprofits, and companies)

Name		Title	
Address			
City	State	Zip	County
Phone	Fax		Email

DRUG SCHEDULES (Check all that apply)

- ☐ Legend drugs
- ☐ Controlled substances
- ☐ Nonprescription drugs
- ☐ Schedule II narcotic
- ☐ Schedule II non-narcotic
- ☐ Schedule III narcotic
- ☐ Schedule III non-narcotic
- ☐ Schedule IV
- ☐ Schedule V (includes pseudoephedrine, ephedrine)
- ☐ Other: _____

If you selected any Drug Schedules above, please provide either:

☐ A copy of the current DEA Registration
Current DEA Registration Number _____ Expiration Date _____

☐ The submission date for the pending DEA Registration Application _____

☐ Yes ☐ No **Is the applicant currently registered with the FDA?**
If yes, provide your FDA Registration Number _____ Expiration Date _____

PRACTICE QUESTIONS

☐ Yes ☐ No Are you operating as a virtual distributor or virtual manufacturer?
If yes:
- ☐ Yes ☐ No Are you required to register in your home state?
- ☐ Yes ☐ No Does the facility have adequate lighting, ventilation, temperature controls, humidity, space, equipment, sanitation, and security, and is the facility free of any infestation and maintained in a clean and orderly condition?

☐ Yes ☐ No Are all Kansas businesses or individuals you conduct business with licensed or registered to possess drugs or devices in Kansas?

DISCIPLINARY INFORMATION

Applicant includes the legal ownership entity as well as each individual, owner, partner, corporate officer, or director.

☐ Yes ☐ No **1.** Has the applicant been convicted under any federal, state, or local law relating to drug samples, wholesale or retail drug distribution, manufacturing, dispensing, or distribution of any drug or controlled substance?

☐ Yes ☐ No **2.** Has the applicant been convicted of or entered a plea of no contest to any felony?

☐ Yes ☐ No **3.** Has any license or registration, currently or previously held by the applicant been denied, disciplined, censured, revoked, suspended, or surrendered for the dispensing, manufacture or distribution of any drug or controlled substance?

☐ Yes ☐ No **4.** Has the applicant ever furnished false or fraudulent material on any application made in connection with the dispensing, manufacture or distribution of any drug?

If yes to any of the above questions, please attach Form S-300: Disciplinary History.

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☐Yes ☐No **5.** Has the applicant complied with all registration requirements under any previous or current licenses or registrations?

☐Yes ☐No **6.** Has the applicant complied with all requirements to maintain and make available to the Board or to any federal, state, or local law enforcement officials those records required by the Food, Drug, and Cosmetic Act?

☐Yes ☐No **7.** Has each employee or associate engaged in any prescription drug wholesale distribution activity had education, training, or experience sufficient for that individual to perform assigned functions in such a manner as to provide assurance that the drug product, quality, safety, and security will at all times be maintained as required by any federal or state law?

If no to any of the above questions, please attach a detailed explanation along with any relevant documentation.

AUTHORIZED AGENT CERTIFICATION

I declare under penalty of perjury under the laws of the State of Kansas that I understand any permit issued will be issued jointly to the applicant and myself, and I hereby accept responsibility as the authorized agent for such permit, which shall include compliance with the Kansas Pharmacy Act and Kansas Controlled Substances Act.

SIGNATURE _____ DATE SIGNED _____

OWNER CERTIFICATION

I declare under penalty of perjury under the laws of the State of Kansas that I have read and understand this application and that the information provided is true, correct, and complete to the best of my knowledge.

SIGNATURE _____ DATE SIGNED _____